



**Sloane  
Hospital  
for Women**

COLUMBIA UNIVERSITY  
COLLEGE OF PHYSICIANS & SURGEONS  
AND  
NEW YORK PRESBYTERIAN HOSPITAL



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ROGERIO A. LOBO, M.D.  
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CHAIRMAN OF THE DEPARTMENT  
DIRECTOR OF SERVICES

July 14, 2000

Dockets Management Branch (HF A-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Docket # OOD:1278

Dear Officer:

I am writing in reference to the publication of your draft guidance document entitled "Guidance for Industry: Female Sexual Dysfunction".

Lack of desire is the single most common and most important sexual problem in women. Sexual response should be measured as a multidimensional assessment of receptivity, (satisfaction with frequency of sexual contact, arousal, intensity), and desire (sexual fantasies/thoughts). This document does not reflect appropriate measurements of female sexual function. It also overemphasizes the notion of "personal distress" which is ambiguous and is hard to quantify.

The primary endpoint for this document is frequency of sexual activity, which results in orgasm. This is a male oriented perspective and cannot be considered an adequate definition for female sexual activity. It is inappropriate to model sexual dysfunction in women after the performance oriented definition used for men. There is nothing indicative within this document that sexual activity without orgasm is significant and meaningful.

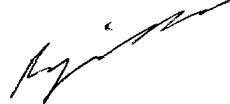
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The symptoms listed should be designed to assess improvements in the Quality of Life, and not specifically to increase the frequency of sexual activity. Enhancing Quality of Life, increased desire accompanied by satisfaction with activity, rather than purely performance should be the definitive reason for treatment. Improvement in interest, motivation, pleasure, and satisfaction should be regarded as the most important goals for intervention. To properly assess the value of the treatment these responses need to be identified and measured.

I urge the agency to reconsider its position.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Rogerio A. Lobo', written in a cursive style.

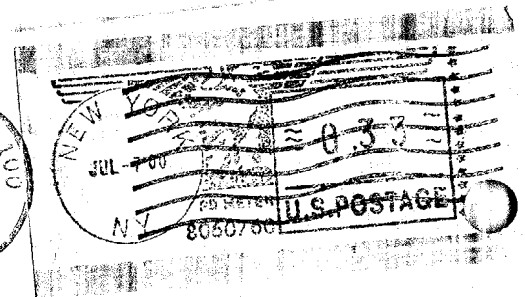
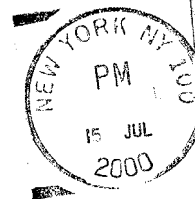
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